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UNITED STATES DISTRICT COURT

CENTRAL DISTRICT OF CALIFORNIA

WESTERN DIVISION

IN RE CONAGRA FOODS, INC.	Case No. CV 11-05379-MMM (AGRx) MDL NO. 2291 CLASS ACTION PLAINTIFFS' OPPOSITION TO EX PARTE APPLICATION FOR ORDER STAYING PROCEEDINGS PENDING OUTCOME OF REFERRAL TO FOOD AND DRUG ADMINISTRATION; DECLARATION OF HENRY J. KELSTON DATE: TIME: DEPT.: JUDGE: Hon. Margaret M. Morrow

Plaintiffs, by their undersigned counsel, respectfully submit this memorandum in opposition to Defendant ConAgra Foods, Inc.'s ("Defendant" or "ConAgra") *Ex Parte* Application for Order Staying Proceedings Pending Outcome of Referral to Food and Drug Administration (Dkt. No. 171) ("Emergency Reconsideration Motion").

Defendant's Emergency Reconsideration Motion fails on both substantive and procedural grounds. As more fully explained below, ConAgra's emergency application is nothing more than an untimely and legally defective motion for reconsideration of an argument that this Court carefully considered and rejected almost two years ago. Having previously lost on this very issue before this Court, ConAgra now improperly seeks reconsideration, based on neither new dispositive law nor new facts, and attempts to mask the defects of its request by framing it as an emergency. Indeed, ConAgra's Emergency Reconsideration Motion illustrates the lengths to which it will go in its attempts to avoid a ruling on the merits of this case.

This Court should stand by its well-reasoned original ruling on this issue and reject ConAgra's misplaced and baseless emergency demand to stay this action indefinitely.

I. BACKGROUND

In 2011, ConAgra moved to dismiss this action on several grounds, including federal preemption. *See* Notice of Motion and Motion to Dismiss Class Action Complaint; Memorandum of Points and Authorities in Support Thereof (Dkt. No. 24) ("Def. 2011 Motion"). In that motion, ConAgra alternatively moved to "dismiss or stay this action under the doctrine of primary jurisdiction, so that the Food and Drug Administration may exercise its jurisdiction, in the first instance, to resolve issues falling within its unique expertise." *Id.* at i. Defendant argued at that time:

> If the Court were to allow this case to move forward, it would forego the benefits of highly-developed agency experience and unique agency resources. As significantly, if this case were to progress to trial, there would be a serious risk that the uniform federal policy in this area would be distorted by inconsistent standards arising from state tort litigation.

Id. at 19.

This Court decisively rejected ConAgra's request to stay or dismiss on the basis of primary jurisdiction argument, holding that:

> Application of the doctrine is not appropriate here. "[V]arious parties have repeatedly asked the FDA to adopt formal rulemaking to define the word natural and the FDA has declined to do so because it is not a priority and the FDA has limited resources. Moreover, this is not a technical area in which the FDA has greater technical expertise than the courts—every day courts decide whether conduct is misleading."

Order Granting Defendant's Motion to Dismiss (Dkt. No. 54) (the "2011 Order") at 14, *quoting Lockwood v. Conagra Foods, Inc.*, 597 F. Supp. 2d 1028, 1035 (N.D. Cal. 2009). In rejecting ConAgra's primary jurisdiction argument, the Court specifically noted that the argument was particularly "unavailing when there is no indication that the FDA intends to provide guidance on use of the term 'natural' in the immediate future." *Id.*

There has been no material change in the relevant facts or controlling law since 2011, and ConAgra's contention that FDA will address this issue in the foreseeable future is aspirational at best. Indeed, what ConAgra is actually seeking is for this Court to second-guess its own well-reasoned ruling and reverse itself because a district court from another jurisdiction has issued a ruling more to ConAgra's liking. This is not the type of new law or new facts justifying

reconsideration, nor is it an emergency warranting an *ex parte* motion. As more fully explained below, in its Emergency Reconsideration Motion, ConAgra rehashes the same primary jurisdiction arguments that the Court considered and rejected two years ago, citing to two non-controlling and unpersuasive opinions, and then contradicts a principal argument it made in 2011.

This Court's 2011 Order should not be reconsidered or reversed.

II. ARGUMENT

A. *Ex Parte* Treatment Is Unwarranted Here

ConAgra offers no valid reason for emergency consideration of its present reconsideration motion. Indeed, as this Court recently held in *Morales v. Prolease PEO, LLC*, No. 11-CV-10389, 2011 WL 6740329 (C.D. Cal. Dec. 22, 2011),

> The "opportunities for legitimate ex parte applications are extremely limited…. [E]x parte applications contravene the structure and spirit of the Federal Rules of Civil Procedure and the Local Rules of this court…. They impose an unnecessary administrative burden on the court and an unnecessary adversarial burden on opposing counsel who are required to make a hurried response under pressure, usually for no good reason. Thus, the use of such a procedure should be limited to instances in which: (1) there is the threat of immediate or irreparable injury; (2) there is danger that notice to the other party may result in the destruction of evidence or the party's flight; or (3) the party seeks a routine procedural order that cannot be obtained through a regularly noticed motion.

Id. at *1 (internal citations and quotation marks omitted).

The present situation does not come close to meeting that standard. Such "fire alarm pulling" by ConAgra does nothing but impose unnecessary and unjustified burdens on the Court and Plaintiffs.

The only rationale ConAgra offers for its emergency submission is that "a major purpose of this request is to minimize unnecessary expenditures, and … the first available hearing date on the Court's calendar is in late October," a bit more than two months hence. Emergency Reconsideration Motion at 1. Even if accurate, this fact does not constitute a threat of immediate or irreparable injury or any of the other circumstance that justifies use of *ex parte* procedures.

Further, ConAgra's asserted rationale is belied by its conduct prior to filing the application. First, ConAgra waited nearly a month after the issuance of the decision that purportedly created this "emergency," *Cox v. Gruma*, No. 12-CV-6502, Slip Op., Dkt. No. 68 (N.D. Cal. Jul. 11, 2013).

Second, Defendant initially reached out to Plaintiffs to collaborate on a joint submission on this issue in the form of an updated case management statement. Despite their strong opposition to ConAgra's stay demand, Plaintiffs agreed to submit this issue to the Court jointly and offered to provide Plaintiffs' portion of the joint submission to ConAgra within three to four days after receiving ConAgra's portion.[1] Upon receipt of Plaintiffs' response, ConAgra immediately rejected Plaintiffs' proposed schedule and, instead, proffered this *ex parte* motion, advising Plaintiffs that they were seeking emergency treatment from the Court on this issue. The factual history demonstrates that the timely submission of this issue and the avoidance of unnecessary expenditures were not ConAgra's primary motivations in choosing to file this application on emergency basis.[2]

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[1] The relevant emails are attached as Exhibits A and B to the Declaration of Henry J. Kelston, submitted herewith.

[2] ConAgra's claim that emergency treatment is warranted based on its cost-consciousness on GMO-related issues is also belied by its substantial expenditures on campaigns to defeat GMO-related initiatives when it believes that such legislation or other rulemaking will hinder its business interests. For example, ConAgra donated more than $1 million to oppose California's Proposition 37

There is no threat of immediate or irreparable injury here, no danger of evidence destruction or flight, and ConAgra is not seeking a routine procedural order. In short, ConAgra's filing of this motion on an emergency basis is neither warranted by existing law nor by a nonfrivolous argument for extending, modifying, or reversing existing law or for establishing new law. *See* Fed.R.Civ.P. 11. On this basis alone, ConAgra's Emergency Reconsideration Motion should be denied.

B. ConAgra's Application Fails To Satisfy The Reconsideration Standards

In addition to its procedural defects, ConAgra's Emergency Reconsideration Motion also fails substantively. While Defendant studiously avoids using the word "reconsideration" in its *ex parte* application, it effectively concedes that its motion is, in fact, a reconsideration motion when it erroneously asserts that this Court's 2011 Order is not dispositive of the current motion because "this motion is based on new developments – both factual and legal – that postdate the Court's prior ruling." Emergency Reconsideration Motion at 5. New facts or new law are the relevant standards for a motion for reconsideration. *See* Local Rule 7-18.

It is unsurprising that ConAgra seeks to camouflage its present motion as something other than a reconsideration demand. Motions for reconsideration are disfavored and rarely granted, *Brown v. United States*, No. 09-CV-8168, 2011 WL

GMO labeling law in November 2012. Daniel Willis & Leigh Poitinger, *Proposition 37 donor and finance information*, MercuryNews.com (Sept. 18, 2012, 01:17 PM), http://www.mercurynews.com/elections/ci_21386000?appSession=86160328214226 (last visited August 7, 2013). ConAgra's emergency demand here has nothing to do with cost-consciousness; rather, it is part and parcel of ConAgra's overall strategy to evade both responsibility and liability for misleading consumers about the GMO content of Wesson Oils.

333380 (C.D. Cal. Jan. 31, 2011), and the standards for obtaining reconsideration of a court's prior decision are strict. The Ninth Circuit has held that "[r]econsideration is appropriate if the district court (1) is presented with newly discovered evidence, (2) committed clear error or the initial decision was manifestly unjust, or (3) if there is an intervening change in *controlling* law." School Dist. No. 1J v. AC and S, Inc., 5 F.3d 1255, 1263 (9th Cir. 1993) (emphasis added). ConAgra here satisfies *none* of these standards.

Correspondingly, Local Rule 7-18 provides, in relevant part:

> A motion for reconsideration of the decision on any motion may be made only on the grounds of . . . (b) the emergence of new material facts or a change of law occurring after the time of such decision . . . No motion for reconsideration shall in any manner repeat any oral or written argument made in support of or in opposition to the original motion.

Local Rule 7-18. ConAgra's Emergency Reconsideration Motion also fails to meet *any* of these standards, as it cites neither a change in the material facts nor an intervening change in the law under which the Court previously rejected ConAgra's primary jurisdiction argument. Moreover, ConAgra blatantly violates the Local Rule 7-18 prohibition against repeating arguments made in support of the prior motion.

ConAgra, however, contends that there is a new material fact that justifies its demand that this Court reconsider and reverse its 2011 decision rejecting ConAgra's primary jurisdiction argument in this case.[3] Specifically, ConAgra

[3] Although Defendant asserts that its Emergency Reconsideration Motion is "based on new developments–both factual and legal," Emergency Reconsideration Motion at 5, it fails to plead or otherwise substantiate what it contends to be a change in the relevant law.

writes: "The fact that the FDA has now been asked specifically by two federal judges to consider issuing a response on the GMO/natural issue is a new material fact, and one that occurred long after this Court's 2011 decision." Emergency Reconsideration Motion at 5.[4]

While the district courts in *Cox* and *Barnes* did stay those cases and refer to the FDA the question of whether products containing bioengineered ingredients may or may not be labeled natural, Defendant's characterization of these opinions as a "new, material fact" justifying reconsideration is spurious.

First, as this Court noted in its 2011 Order, "'[v]arious parties have repeatedly asked the FDA to adopt formal rulemaking to define the word natural and the FDA has declined to do so because it is not a priority and the FDA has limited resources.'" 2011 Order at 14 (quoting Lockwood, 597 F. Supp. 2d at 1035). Thus, the recent referrals by the two district courts do not constitute a "new" fact in any sense; they are just two more in a long line of such requests from various sources dating back to 2011 and beyond.

Nor are the recent referrals material. In the past, the FDA has explicitly declined to address the meaning of "natural" claims in direct response to a district court referral similar to those on which Defendant here relies. In *Coyle v. Hornell Brewing Co.*, No. 08-CV-2797, Slip Op., Dkt. No. 119 (D.N.J. Sept. 23, 2010) (copy attached), in which the issue was whether a "natural" label was misleading when placed on a product containing high fructose corn syrup, the district court

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[4] The two recent opinions to which Defendant refers are *Cox v. Gruma*, No. 12-CV-6502, Slip Op., Dkt. No. 68 (N.D. Cal. Jul. 11, 2013), and *Barnes v. Campbell Soup Co.*, No. 12-CV-5185, Slip Op., Dkt. No. 55 (N.D. Cal. Jul. 25, 2013). Defendant also cites, but does not rely on, *Van Atta v. General Mills, Inc.*, No. 12-CV-2815, Slip Op., Dkt. No. 51 (D. Colo. Jul. 17, 2013), a magistrate judge's recommendation of a stay pending possible FDA action on the referral made in *Gruma*.

granted a six month stay and referred the issue to the FDA. The court lifted the stay after receiving a letter from the FDA stating that for the FDA to resolve that issue, it would likely take "two to three years," a timeframe "that would likely not be useful to the Court in resolving the current case." *Id.* The FDA further stated that "[p]roceedings to define 'natural' do not fit within [the] current priorities" of the agency. *Id.* Indeed, the FDA has shown no inclination in the past to speak to this issue and has given no indication that it intends to do so now – despite these new orders.[5]

Moreover, while these two courts ruled as they did, other courts – including this Court – have ruled otherwise. Indeed, as recently as May 2013, in *Janney v. General Mills*, No. 12-CV-3919, 2013 WL 1962360 (N.D. Cal. May 10, 2013), a Northern District of California court rejected the defendant's request to stay or dismiss on primary jurisdiction grounds, holding, in pertinent part, that:

> [I]n repeatedly declining to promulgate regulations governing the use of "natural" as it applies to food products, the FDA has signaled a relative lack of interest in devoting its limited resources to what it evidently considers a minor issue, or in establishing some "uniformity in administration" with regard to the use of "natural" in food labels. Accordingly, any referral to the FDA would likely prove futile.

Id. at *7.

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[5] Plaintiff's note that the *Cox* and *Barnes* orders staying their respective cases have not formally initiated administrative action through their referrals because "[t]here is no formal transfer mechanism between the courts and the agency; rather, upon invocation of the primary jurisdiction doctrine, the parties are responsible for initiating the appropriate proceedings before the agency." *See Syntek Semiconductor Co. Ltd. v. Microchip Technology Inc.,* 307 F.3d 775, 782 n3 (9th Cir. 2002) (internal citation omitted, emphasis added).

This Court's 2011 Order declining to dismiss or stay the case on grounds of primary jurisdiction places it squarely in line with the majority of courts that have considered the issue. *See Janney v. General Mills, supra; Coyle v. Hornell Brewing Co.*, *supra*; *Krzykwa v. Campbell Soup Co.*, No. 12-CV-62058, 2013 WL 2319330, at *4 (S.D. Fla. May 28, 2013) (holding that "Defendant's arguments that the claims should be dismissed under the primary jurisdiction doctrine [are] also misplaced because the FDA has repeatedly declined to adopt formal rule-making that would define the word 'natural'"); *Jones v. ConAgra Foods, Inc.*, 912 F. Supp. 2d 889, 902 (N.D. Cal. 2012) ("The FDA's inaction with respect to the term 'natural' implies that the FDA does not believe that the term 'natural' requires 'uniformity in administration. . . . Accordingly, courts need not refer such claims to the FDA pursuant to the primary jurisdiction doctrine.") (quotations omitted); *Holk v. Snapple Beverage Corp.*, No. 07-CV-3018, 2010 WL 4065390 (D.N.J. Oct. 15, 2010) (lifting stay in light of the FDA letter in *Coyle*); *Wright v. Gen. Mills, Inc.*, No. 08-CV-1532, 2009 WL 3247148, at *3 (S.D. Cal. Sept. 30, 2009) ("Based on the FDA's consistent determination that the term 'natural' does not need specific definition, state law claims based upon the use of the term 'natural' [do] not [present] an issue of first impression, do[ ] not require technical expertise within the special competence of the FDA, and [do] not [raise] a particularly complicated issue outside the ability of the Court to consider and decide."); *Lockwood v. ConAgra Foods, Inc*., 597 F. Supp. 2d 1028, 1035 (N.D. Cal. 2009) ("At a minimum, various parties have repeatedly asked the FDA to adopt formal rulemaking . . . and the FDA has declined to do so because it is not a priority and the FDA has limited resources."). *Accord*, *Astiana v. Ben & Jerry's Homemade, Inc.*, No. 10-CV-4387, 2011 WL 2111796 (N.D. Cal. May 26, 2011).

Finally, with regard to the *Cox* and *Barnes* decisions on which Defendant so heavily relies, those opinions are not binding on this court and, therefore, could not

constitute a material change in the law. *Saunders v. Louise's Trattoria*, No. 07-CV-1060, 2007 WL 4800589 (C.D. Cal. Nov. 19, 2007). In *Saunders,* the court denied a motion for reconsideration after two courts in the same district issued contrary decisions, noting: "This 'change' in the law is neither material nor binding. Saunders simply asks the Court to join the newly created minority position in a district-wide split solely because it exists." *Id.* at 1; *see also Kentera v. Fremont Inv. & Loan*, No. 10-CV-8259, 2012 WL 1438683, at *2 (D. Ariz. Apr. 26, 2012) ("A decision by another district court is not binding on this court and therefore does not constitute 'an intervening change in controlling law' sufficient to merit reconsideration.")(quoting *Turner v. Burlington N. Santa Fe R.R. Co.*, 338 F.3d 1058, 1003 (9th Cir. 2003)); *Buzayan v. City of Davis,* No. 06-CV-01576, 2012 WL 1413886 (E.D. Cal. Apr. 23, 2012) (denying motion for reconsideration based on non-binding district court decisions).

ConAgra also asserts that reconsideration is warranted because the FDA recently revised its website to note that the agency is currently considering "citizen petitions regarding genetically engineered foods, including the labeling of such foods." Emergency Reconsideration Motion at 5. That the FDA receives citizen petitions about GMOs is not a new fact, let alone a material one. As summarized by the court in *Janney,* 2013 WL 1962360, at *4:

> In 2002, the Center for Science in the Public Interest asked the FDA to take action against Ben & Jerry's, an ice cream producer that labeled its products "all natural." The FDA's response was that defining "natural" was "not among the FDA's current enforcement priorities." In 2006, the Sugar Association petitioned the FDA to define "natural," and FDA likewise declined to do so. In 2010, a number of U.S. District Courts issued six-month stays of pending litigation over the use of "natural" in beverages containing high-

> fructose corn syrup, in the hopes that FDA would formally define "natural." Nevertheless, the FDA declined to do so.

Id.

In fact, ConAgra raised this very point in its Reply Memorandum in 2011, writing: "Indeed, just such a petition has been filed with the FDA during the course of the briefing on this Motion. On October 4, 2011, the Center for Food Safety filed a Citizen Petition with the FDA acknowledging the agency's current policy – *i.e.*, no special labeling required for bioengineered foods – and arguing strenuously that the policy should be changed." Defendant ConAgra Foods, Inc. Reply Memorandum of Law in Support of Motion to Dismiss Class Action Complaint (Dkt. No. 39)("Def. 2011 Reply Memo") at 13.[6] Still, the FDA has not ruled on the issue and has given no indication that in intends to do so in the near future. Based on the FDA's handling of this similar issue, there is no reason to think that resolution of the "natural" issue will occur anytime soon, nor has ConAgra supplied any basis for this Court to conclude otherwise.

Moreover, FDA action regarding "genetically engineered foods, including the labeling of such foods," would not be determinative of the issue in this case—whether ConAgra's voluntary labeling of Wesson oils as "natural" misled consumers regarding the presence of GMOs in the products.

In sum, the recent referrals to the FDA by the *Cox* and *Barnes* courts represent neither a change in material facts nor controlling law, and the revision of

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[6] ConAgra's argument concerning citizen petitions should be disregarded in its entirety as repeating arguments made in support of the original motion, in violation of Local Rule 7-18. *Compare* Emergency Reconsideration Motion at 5 with Def. 2011 Reply Memo at 13. Similarly, Defendant's arguments regarding the "likelihood of inconsistent determinations," Emergency Reconsideration Motion at 6, should be disregarded as mere repetition of its earlier argument that the failure to stay the action could result in "inconsistent standards." Def. 2011 Motion at 19.

the FDA website regarding citizen petitions is of no significance whatsoever. The existence of citizen petitions to the FDA on the subject of natural claims and/or GMOs did not persuade the Court to stay this case in 2011, and it does not support a request for reconsideration in 2013. The application currently before the Court is nothing more than a motion for reconsideration asking the Court to reverse a prior decision and join a newly created minority position in a split among district courts. This Court should thus deny ConAgra's emergency motion.

C. As This Court Correctly Held in 2011, The Doctrine Of Primary Jurisdiction Is Not Applicable

For the reasons stated in Plaintiffs' Opposition to Defendant's Motion to Dismiss (Dkt. No. 34), filed on October 10, 2011, the doctrine of primary jurisdiction was and remains inapplicable to this case. Plaintiffs' primary arguments will not be repeated here, in accordance with Local Rule 7-18.

It should be noted, however, that ConAgra's current argument in favor of primary jurisdiction directly contradicts the argument it made in 2011. In its current Emergency Reconsideration Motion, ConAgra seeks a stay of this case because the FDA might, at some future time, take action regarding the term "natural" as it applies to foods containing GMOs. However, in its 2011 stay/dismissal demand, ConAgra asserted that: "*Plaintiff's claims do not depend on the FDA's definition of 'natural.'* The question of whether ConAgra's labels are improper is answered by a different body of regulatory guidance and activity – that is, the FDA's actions on the use and marketing of bioengineered foods and the regulations governing common and usual names and ingredient lists."[7] Def. 2011

[7] Lest there be any question about ConAgra's position, in its 2011 Reply Memorandum, ConAgra asserted that: "*ConAgra's preemption claim is not based on the FDA's regulation of the term 'natural,' nor on the field of 'natural' products*. ConAgra's preemption claim is based on the FDA's considered determination that whether foods have bioengineered sources is not material and

Motion at 17 (emphasis added). And, as to that issue, ConAgra claimed that the FDA had already acted, stating: "[T]he FDA has considered at length the question put at issue by Plaintiff's claim and has published detailed guidance." Def. 2011 Memo at 13.

Furthermore, even if the FDA does respond to the request made in *Cox v. Gruma* — "whether and under what circumstances food products containing ingredients produced using bioengineered seed may or may not be labeled 'Natural' or 'All Natural' or '100% Natural'" — ConAgra has given no indication that it is prepared to abide by an FDA ruling, should one ever be issued. Indeed, despite its attempt to shut down this litigation on its unfounded aspirations of impending FDA action, should the FDA ultimately conclude that foods comprised of or containing GMOs are not "natural," it is a virtual certainty that ConAgra will change course once again and argue that its misleading representations about Wesson Oil occurred prior to the FDA's ruling and that, consequently, the ruling is irrelevant to their liability in this case. Therefore, unless ConAgra is prepared to confess judgment should the FDA rule in that manner, an FDA ruling – when it occurs, if ever – will not dispose of this case, and provides no basis to shut down this case now.

D. Plaintiffs Would Be Prejudiced By A Stay

Despite ConAgra's protestations that a "stay will not prejudice Plaintiffs," Emergency Reconsideration Motion at 6, Plaintiffs will indeed be materially prejudiced by a stay.[8]

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need not be disclosed on a label, and on the FDA's consultation process, in which food safety and labeling evaluations are made for every new bioengineered food that enters the marketplace." Def. 2011 Reply Memo at 12 (emphasis added).

[8] ConAgra's present request for a six month stay is disingenuous, as the FDA has clearly indicated in the past that any rulemaking effort concerning the meaning of "natural" on food labels would likely take two to three years. *See* discussion of

First, further delaying discovery will erode the Plaintiffs' ability to discover the facts concerning ConAgra's use of bioengineered ingredients in Wesson Oils and the continued marketing of those products as "natural." The memories of ConAgra witnesses with the most knowledge regarding ConAgra's relevant policies, practices and decisions will continue to fade as time passes.

Plaintiffs are further prejudiced by delay because each and every day, ConAgra is continuing to mislead members of the proposed Class by marketing Wesson Oils as 100% Natural when they are not. This Court should not prejudice Plaintiffs by making them wait for resolution of this controversy even longer.

Other courts have recognized that stays pending FDA action on consumer issues work real and substantial prejudice to plaintiffs. In *Ackerman v. Coca-Cola Co.*, CV-09-0395 (JG), 2010 WL 2925955 (E.D.N.Y. July 21, 2010), the court rejected defendant's primary jurisdiction argument, observing that

> deferral to the FDA is unlikely to result in a timely resolution of plaintiffs' claims. The FDCA does not provide a private right of action, and there is no reason to believe the plaintiffs could obtain a timely determination from the FDA concerning the merits of their claims. *See Golden Hill Paugussett Tribe of Indians v. Weicker,* 39 F.3d 51, 60 (2d Cir.1994) (noting, in considering issue of primary jurisdiction, that "[t]here clearly is a public interest in reasonably prompt adjudication").

Id. at *14. Similarly, in *In re Colgate-Palmolive Softsoap Antibacterial Hand Soap Mktg. & Sales Practices Litig*., 12-MD-2320-PB, 2013 WL 1124081 (D.N.H. Mar. 18, 2013), where an FDA ruling on the relevant issue would have taken at

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Coyle v. Hornell Brewing Co., *supra* at 8. The stay sought by ConAgra here is for as long as it takes for the FDA to act, if it ever does, *i.e.*, an indefinite stay.

least fourteen more months, the court denied defendant's motion to dismiss on primary jurisdiction grounds, stating: "Any minimal value that an FDA ruling might have on the resolution of this case is greatly outweighed by the harm that the plaintiffs will suffer if the action is delayed, potentially for several years, until the FDA makes a determination." *Id*. at 8. *Accord, In re Dial Complete Mktg. & Sales Practices Litig.*, 11-MD-2263-SM, 2013 WL 1222310 (D.N.H. Mar. 26, 2013).

A stay pending FDA action in the present case would likely result in a delay of several years. The FDA has stated that it would take two to three years for the agency to resolve the meaning of the word "natural" on food labels if it ever decided to address the issue (which, to date, it has not), and acknowledged that a delay of that length meant that any resulting agency action "would likely not be useful to the Court" in resolving the pending consumer action. *See discussion of Coyle v. Hornell Brewing Co.*, *supra* at 8.

Thus, as the FDA and the courts have recognized, consumers suffer substantial prejudice if they are denied access to the courts to redress deceptive labeling claims and are, instead, required to wait years for even the possibility of agency action. Such prejudice would be the certain result of a stay in this case.

III. CONCLUSION

For all of the foregoing reasons, Plaintiffs respectfully submit that ConAgra's Ex Parte Application for Order Staying Proceedings Pending Outcome of Referral to Food and Drug Administration be denied in all respects.

DATED: August 7, 2013

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Interim Class Counsel

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

LAUREN COYLE, *on behalf of herself and all those similarly situated,* Plaintiff, v. HORNELL BREWING CO., et al., Defendants.	Civil No. 08-2797 (JBS) ORDER LIFTING STAY

The Court hereby advises all counsel of the receipt of the attached letter dated September 16, 2010, received September 21, 2010, from Michael M. Landa, Acting Director, Center for Food Safety and Applied Nutrition, U.S. Food and Drug Administration, declining to provide an FDA determination of the question whether high fructose corn syrup qualifies as a "natural" ingredient. This Court had referred this issue to the FDA pursuant to the Order of June 1, 2010 [Docket Item 115] and the Order of June 25, 2010 [Docket Item 118], and had stayed this litigation for six (6) months pending this referral.

It now appears that the stay should be lifted so that the case may proceed, and the Plaintiff's remaining claims may be prosecuted and that a schedule should be set for the reinstatement of Plaintiff's motion for class certification [Docket Item 108] and for briefing and hearing of that motion;

and for these purposes a short scheduling conference will be convened by telephone on Wednesday, September 29, 2010 at 10:00 A.M.;

IT IS, this **23rd** day of **September, 2010**, hereby

ORDERED that the temporary stay of litigation from June 25, 2010 will be dissolved and the case may proceed; and it is further

ORDERED that the Court will convene a telephone scheduling conference of all counsel on **Wednesday, September 29, 2010 at 10:00 A.M.**, and Plaintiff's counsel is requested to arrange for the telephone conference call at that time.

s/ Jerome B. Simandle
JEROME B. SIMANDLE
U.S. District Judge

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
College Park, MD 20740

SEP 16 2010

RECEIVED
SEP 21 2010
JEROME B. SIMANDLE
U.S. DISTRICT JUDGE

The Honorable Jerome B. Simandle
U.S. District Judge
United States Courthouse
One John F. Gerry Plaza
P.O. Box 888
Camden, New Jersey 08101

Re: Coyle v. Hornell Brewing Co., Inc., et al.
Civil Number 08-2797 (JBS-JS)

Dear Judge Simandle:

This is in response to your letter dated June 25, 2010, referring to the Food and Drug Administration ("FDA") for an administrative determination under 21 C.F.R. 10.25(c) the question of whether high fructose corn syrup ("HFCS") qualifies as a "natural" ingredient. For the reasons explained below, we respectfully decline to provide such a determination.

First, for the FDA to resolve whether HFCS qualifies as a "natural" ingredient in defendants' beverages, in the absence of a pre-existing regulatory definition, the agency would expect to act in a transparent manner by engaging in a public proceeding to establish the meaning of this term. Given the issues involved, making such a determination without adequate public participation would raise questions about the fairness of FDA's action. FDA's experience with such proceedings suggests that it would take two to three years to complete. We recognize that such a timeframe would likely not be useful to the Court in resolving the current case.

Second, priority food safety and applied nutrition matters are currently fully occupying the resources that FDA has available for public proceedings on foods matters. For example, the agency is involved in taking actions designed to improve (1) the safety of the food supply and (2) the dietary practices of Americans, because many of the underlying causes of chronic disease – high blood pressure, elevated cholesterol, obesity and diabetes – are the result of lifestyle factors, including unhealthy eating, and are largely preventable. Proceedings to define "natural" do not fit within these current priorities. *See* 21 C.F.R. § 10.25(c).

Consumers currently receive some protection in the absence of a definition of "natural" because the Federal Food, Drug, and Cosmetic Act and FDA's implementing regulations require that all ingredients used in a food be declared on the food's label. Thus, the label provides consumers with information to decide whether to purchase the food. So, for the food product at issue in the above-captioned case, the consumer would know from the label whether the product contained HFCS.

The most relevant statement of the agency's views is provided by the preamble language cited by the Court on page 6 of its June 15, 2010 opinion. The FDA there reiterated its interpretation that "natural" means nothing artificial or synthetic. This interpretation was not established by regulation but it is the most definitive statement of the agency's view. By contrast, Geraldine June's letter, which the Court cited on page 7 of its June 15, 2010 opinion, is an informal communication and does not provide a binding agency interpretation for the Court to follow. The opinions of individual employees do not bind the agency, and FDA has made clear that only the Commissioner can speak definitively for the agency. *See* 21 C.F.R. § 10.85(k); *see also Western Ill. Home Health Care v. Herman,* 150 F.3d 659, 662 (7th Cir. 1998) (agency action not final if only the ruling of subordinate official); *Regenerative Sciences v. FDA,* No. 09-cv-00411, 2010 WL 1258010, at *7 (D. Colo. March 26, 2010) (finding that statements of lower level FDA officials do not rise to level of agency action even when contained in regulatory correspondence); *Genendo Pharmaceutical v. Thompson,* 308 F. Supp.2d 881, 885 (N.D. Ill. 2003) (statements of FDA officials in warning letter do not constitute final agency action).

We hope that this information is helpful to you.

Respectfully,

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